

hydrogenated castor oil ethoxylates, polyglycerol esters of fatty acids, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers, polyoxyethylene-polyoxypropylene block co-polymers, and d-alpha tocopheryl polyethylene glycol 1000 succinate wherein the resulting mixture forms an emulsion upon dilution with an aqueous phase.

REMARKS

The Present Invention

The present invention is directed to a formulation consisting essentially of a fibrate dissolved in at least one oil and an emulsifier that is capable of forming an emulsion upon dilution in an aqueous medium.

The Office Action

The Office Action made the following rejection:

1) claims 1, 3 and 7-12 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lacy et al. (U.S. Patent No. 5,645,856).

Discussion of 35 U.S.C. §103(a) Rejection

The Examiner has rejected claims 1, 3 and 7-12 under 35 U.S.C. §103(a) as being unpatentable over Lacy et al. The Examiner stated that "Lacy et al. (U.S. Patent No. 5,645,856)

teaches a carrier system for a hydrophobic drug (including finofibrate [fenofibrate]) composition comprising (a) a digestible oil (including soybean oil, coconut oil, corn oil, palm oil, cottonseed oil, olive oil, safflower seed oil); (b) a pharmaceutically acceptable surfactant comprising a hydrophilic (including phospholipids, poly[oxy]ethylene sorbitan fatty acid derivatives, castor oil or hydrogenated [ester] castor oil ethoxylates, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropyl[k]ene co-polymers[,] and block co-polymers) and a lipophilic surfactant (including propylene glycol), see in particular col. 3, lines 38-67, cols. 5-9[,] and col. 11[12], lines 22-23, see col. 21[,] example 6, lines 21-31."

The present invention claims compositions consisting essentially of a fibrate dissolved in at least one oil with one emulsifier. Claim 1 as presently amended restricts the selected ^{one oil + one emulsifier} emulsifier to either a lipophilic or a hydrophilic surfactant (not both), and would avoid the use of a surfactant (emulsifier), as disclosed by Lacy et al, comprising a hypophilic surfactant component. Thus the claims are not obvious in view of Lacy et al. and this rejection should be withdrawn.

Conclusion

Applicants respectfully request favorable consideration and allowance of claims 1, 3 and

7-12 as presently amended. If any additional fees are incurred as a result of the filing of this paper, authorization is given to charge Deposit Account Number 23-0785.

Respectfully submitted,

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Marked-Up Version of Claims

1. (thrice amended) A composition consisting essentially of a fibrate dissolved in at least one oil with one [or more emulsifiers] emulsifier selected from the group consisting of polyoxyethylene sorbitan fatty acid derivatives, sorbitan fatty acid derivatives, polyoxyl-35-castor oil, castor oil ethoxylates, hydrogenated castor oil ethoxylates, polyglycerol esters of fatty acids, fatty acid ethoxylates, alcohol ethoxylates, polyoxyethylene-polyoxypropylene co-polymers, polyoxyethylene-polyoxypropylene block co-polymers, and d-alpha tocopheryl polyethylene glycol 1000 succinate [and combinations thereof] wherein the resulting mixture forms an emulsion upon dilution with an aqueous phase.